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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,651	11/29/2006	Heno Perillo	4705-0120PUS1	5789

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
01/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,651	PERILLO ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-46* is/are pending in the application.

4a) Of the above claim(s) *40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/06; 11/07/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group II (claims 44-46) in the reply filed on August 21, 2008 is acknowledged. The traversal is on the ground(s) that the special technical feature of the application is the compound 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1H-purin-6-(9H)-one. This is not found persuasive because as discussed previously in the restriction requirement mailed July 22, 2008 the special technical feature of a method of making is not the product, but the interaction of the starting material and the ingredients added to it, while the special technical feature of only the composition is the compound 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1H-purin-6-(9H)-one. Furthermore, the examiner is not required to cite prior art in order to establish a lack of unity of invention, but the applicant themselves have acknowledged in the specification that 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1H-purin-6-(9H)-one is known in the art (specification page 1, lines 22-27). This argument is not found to be persuasive and the requirement is still deemed proper and is therefore made FINAL.

Claims 40-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group I, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 21, 2008.

Applicant has submitted two Information disclosure statements (IDS), one on November 07, 2007 and one on May 25, 2006. These two IDS are identical, and thus

only the references on the May 25, 2006 IDS were considered and the IDS on November 07, 2007 was not considered as it is a duplicated. References BB and BD on the May 25, 2006 reference had only an abstract available in English, and thus only the abstract was considered. Reference CA had no summary or translation available in English and as such as not considered.

Applicant has indicated priority to two foreign applications, Brazil PI0305339-3 and Brazil 000022040150576, the latter of which was not received by the patent office. Neither reference is available in English so priority to these documents has not been perfected. The current effective filing date of the instant application is the date of the PCT application, November 25, 2004.

Specification Objections

The disclosure is objected to because of the following informalities: The title is too long, a suggested title would be "Stable injectable solution of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1H-purin-6-(9H)-one". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 44 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perillo et al. (WO 2004/080371 A2) in view of Smith et al. (US 5,378,475).

In claim 44, applicant claims a sterile, stable, pharmaceutical formulation comprising an injectable solution of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1H-purin-6-(9H)-one (also known as gancyclovir, as described by applicant on page 1 of the specification) in its free acid form, diluted in 5% glucose solution, with a pH from 3.0-6.9, in a tri-laminated bag. Perillo et al. teaches administering drugs via a tri-laminated flexible bag containing an active ingredient in a 5% glucose solution (abstract) and specifically describes the layers as an external layer of polyester, intermediate layer of polyethylene, and inner layer of propylene copolymer (page 23, liens 8-10) which is the same as applicant's layers claimed. Perillo et al. further teaches the desired pH for their solution with 5% glucose is between 2.0-5.0, and more specifically between 4.0-5.0

(page 20, line 25 to page 21, line 25). They do not teach gancyclovir, however one of ordinary skill in the art at the time of the invention would recognize that the benefits described by Perillo et al., such as preventing microbial contamination and reducing the risk of errors (abstract) would apply to any drug that is stable and bio-available in an intravenous solution. Smith et al. teaches that ganciclovir was obtained as a free acid form and that the free acid was prepared from the commercially available salt (column 12, lines 55-60), the further teach the purified product in a buffer solution containing 0.65% sodium chloride (column 12, lines 61-63), the solution of Smith et al. is an injectable solution, and it would have been obvious to one of ordinary skill in the art at the time of the invention that a well known and commonly used drug such as gancyclovir (also known as ganciclovir), which is known to be administered in the free acid form in a solution, could be used in the system of Perillo et al. and it would be expected to be preferable over a standard intravenous solution due to the mentioned benefits of the system of Perillo et al. which would be reasonably expected to translate to another drug which can be administered via intravenous solution. It is noted that neither Perillo nor Smith et al. teach the process by which gancyclovir is made, however this is considered a product by process claim and thus the prior art does not have to teach how it is made. In the absence of evidence to the contrary, the gancyclovir taught by Smith et al. is the same as the product obtained by the method of claim 40. Thus claim 44 is unpatentable over Perillo et al. in view of Smith et al.

In claim 46, applicant claims that the solution is a 5% glucose solution and that the pH is within a range of 3.2 to 6.5. As discussed above, Perillo et al. teaches a 5%

glucose solution (abstract) and teaches the preferred pH of the glucose solution to be 4.0-5.0 (page 21, lines 15-25). Thus claim 46 is also unpatentable over Perillo et al. in view of Smith et al.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perillo et al. (WO 2004/080371 A2) in view of Smith et al. (US 5,378,475) as applied to claims 44 and 46 above and further view of Gupta et al. (US 2002/0183394 A1).

In claim 45, applicant claims the composition of claim 44, wherein the solution is a 0.9% sodium chloride solution and the pH is between 4.5-6.9. Perillo et al. actually teaches both glucose and sodium chloride solutions (page 21, lines 1-25) but does not mention the concentration of the sodium chloride. Saline is one of the most commonly used solutions for use intravenously, and contains 0.9% sodium chloride as evidenced by Gupta et al. (page 5, [0063]). Perillo et al. does teach a preferred pH of 4.5-7.5 for the sodium chloride solution (page 21, lines 20-21) and it would have been obvious to one of ordinary skill in the art that the amount of sodium chloride to use in the system of Perillo et al. would be the 0.9% sodium chloride used in saline. Thus claim 45 is unpatentable over Perillo et al. in view of Smith et al. in further view of Gupta et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614